



Informed Consent and HIPAA Authorization Form

Study Title: An Emergency Department-Based Study to Reduce Adolescent Pregnancy Rates

Version Date: September 9, 2019

Consent Name: Patient consent

Principal Investigator: Dr. Cynthia Mollen

Telephone: (215) 590-1944

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

Study Overview

You are being asked to take part in this study because you are a female between 16-18 years old, you are getting care in the Emergency Department, you do not desire pregnancy within the next year, and you are sexually active or may be sexually active in the near future.

The purpose of this research study is to help us understand why female adolescents may or may not initiate contraception after receiving a contraceptive counseling session.

The first part of this study will take place during your visit with the Emergency Department and will last approximately 30 minutes. If you agree to participate, you will be asked to complete:

- a confidential contraceptive counseling session with a Advanced Practice Provider that will last about 10-15 minutes
- questionnaires
- a follow-up phone call

You may also be invited to return to CHOP for an optional follow-up interview after 8 weeks from your Emergency Department visit.

The risks in this study are considered minimal and include momentary embarrassment or discomfort when answering questions and breach of confidentiality. You will not benefit directly from participating in this study.

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

If you are interested in learning more about the study, please continue to read below.

What are the study procedures?

If you agree to participate, you will first complete a questionnaire regarding demographics and current contraceptive preferences. Then, an Advanced Practice Provider will come in to do a confidential contraceptive counseling session with you that will last about 10-15 minutes. This session may be audio recorded for study purposes. As a part of this study, you will complete a questionnaire to provide information on sexual history and feedback on the counseling you received, and to assess your intent to use contraception, your contraceptive preferences, and your knowledge of sexual health. These processes will take approximately 30 minutes.

You may also be invited for an optional follow-up interview after 8 weeks from your Emergency Department visit. During this interview, a trained member of our study staff will come interview you about your decision to start or change your contraception method.

What will be done with my data during this study?

During the study, we will collect information from you regarding your sexual health history and contraceptive preferences. If you participate in the optional follow-up interview, we will be recording your responses for transcription purposes. By agreeing to participate in the study, you agree to share this data with CHOP for research purposes.

What are the risks of this study?

Though the risks in this study are considered minimal, taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks of Counseling, Questionnaires, and Follow-up Interview:

There are no physical risks, but you may experience momentary embarrassment or discomfort when answering questions during the counseling session, on the questionnaire, or during the follow-up interview. You can choose not to respond to any questions that make you too uncomfortable. If, after answering the questions, you want to talk with someone, please let us know and we can arrange for you to speak with a social worker or someone from our research team.

Risks of Sharing Data:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

We will make every effort to keep the data in this study private. We will do this by keeping your data labeled with only a study ID number, not your name. The name and number code will be kept in a password protected secure research database. This way no one outside the research team can look up your data. We will keep information that identifies you in a separate place from your data.

There also is a risk to confidentiality when using the internet or a mobile network. By providing your telephone number, the study team may communicate with you regarding setting up appointments, and any other non-clinical, study related communication. Please be aware of the following:

Corresponding through text messaging is not a secure method of sending information and others may be able to access the information sent.

The information may not be secure if storing or viewing the permission/assent document on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena.

Information that is sent through text messaging may be kept on the Hospital's or your service provider's (Google, Yahoo, MSN, etc.) network servers. Unlike paper copies, e-copies delivered directly to your PED may not be able to be permanently removed.

The Hospital is not liable for any security breaches of your information sent by text messaging.

Are there any benefits to taking part in this study?

You may benefit from more in-depth contraceptive counseling than you may have received if you were not participating in this study. In addition, the knowledge gained from this study may help doctors better provide contraceptive services for Emergency Department teens in the future.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must provide written consent to study procedures. Because contraceptive counseling is a confidential health service, your parent/ guardian does not need to consent for your participation.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you choose not to take part in this study, you can still receive contraceptive counseling and obtain access to birth control/ contraception as part of your regular care.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if

- The study is stopped.

- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from the questionnaires discussed above, medical records, procedures, interviews, and tests. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information.

They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The Data Safety Monitoring Board (DSMB) who monitors the safety of this study;
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury, or disability.
- The National Institutes of Health who is sponsoring this research.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By giving your consent, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Your records from this study (research records) will be maintained separately from your medical records. The identifiable information from this study will be destroyed 6 years after the study is completed.

Certificate of Confidentiality (CoC)

CHOP IRB#: «ID»

Effective Date: «ApprovalDate»

Expiration Date: «ExpirationDate»

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information could be shared for:

- other scientific research;
- your medical treatment

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Cynthia Mollen
The Children's Hospital of Philadelphia
Department of Emergency Medicine
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

Text messaging rates may apply.

The NIH is providing financial support and material for this study. For participants attending an in-person follow-up interview, the NIH will also provide financial support for the following:

- Cost of parking at CHOP or reimbursement for SEPTA transport

Will you be paid for taking part in this study?

- Participants who complete the contraceptive counseling and feedback questionnaires will be given a \$20 gift certificate for their time and effort.
- Participants who complete the optional, post-counseling interview will receive an additional \$20 gift certificate for their time and effort.

If you receive payment using a bankcard, the bank will have access to some personal information in order to process your payment. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Cynthia Mollen, at 215-590-1944. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What will be done with my data when this study is over?

We will use and may share data for future research. It may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

OPTIONAL

You may be contacted by a study team member about completing a post-counseling interview at least 8 weeks after your contraceptive counseling session. This in-person (or over-the-phone, if necessary) interview will be conducted by a trained interviewer to understand your preferences in pursuing (or not pursuing) contraceptive options. All interviews will be audio recorded, and data obtained during the interviews will be professionally transcribed for data analysis by the study team. This is an optional component.

_____ (initials) I agree to participate in the optional follow-up interview, if contacted.

_____ (initials) I do not wish to take part in this optional part of the research.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research *This documentation page will be used in cases where the patient is providing consent for themselves.*

The research study and consent form have been explained to you by:

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your participation. You are also authorizing the use of your health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

Name of Subject

Signature of Subject

Date

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research This documentation page will be used when parental permission is obtained. **Note: Assent must also be obtained on the next page.**

The research study and consent form have been explained to you by:

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject

Name of Authorized Representative
(if different than subject)

Date

Signature of Authorized Representative

Relation to subject:

☐ Parent ☐ Legal Guardian

Child Assent to Take Part in this Research Study This documentation page will be used when parental permission is obtained. Note: Parental permission must also be obtained using the previous page.

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

Person Obtaining Assent

Signature of Person Obtaining Assent

Date

This study has been explained to me and I agree to take part.

Signature of Subject

Date